

RULEMAKING NOTICE FORM

Notice Number **2016-134**

Rule Number

**He-P 4031.03 (various),
4031.04 (various)& He-P
4031.06**

1. Agency Name & Address: NH Dept. of Health & Human Services Division of Public Health Services Radiological Health Section (RHS) 29 Hazen Drive Concord, NH 03301	2. RSA Authority: RSA 125-F:5, IV & V
	3. Federal Authority: _____
	4. Type of Action:
	Adoption X
	Amendment X
	Repeal _____
	Readoption _____
	Readoption w/amendment _____

5. Short Title: **General Licenses, Source Material, Byproduct Material Other Than Source Material and General Licenses for Certain Items and Self-Luminous Products Containing Radium-226**

6. (a) Summary of what the rule says and of any proposed amendments:

He-P 4031 establishes general licenses for the possession and use of byproduct material and a general license for ownership of byproduct material. The general license provided in He-P 4031 is subject to general provisions in other rules in He-P 4000.

The Department of Health and Human Services (Department) proposes to amend He-P 4031 by amending He-P 4031.03 and He-P 4031.04 and adopting a new section He-P 4031.06. The proposal amends He-P 4031.03 by adding a new paragraph (f), which requires a person to have a specific license before initially transferring or distribution source material to a general licensee. The proposal adds a new section He-P 4031.06 which requires a general license in order to acquire, receive, possess, use, or transfer of certain items and self-luminous products containing radium-226. The proposal deletes paragraph He-P 4031.04(n) and holds He-P 4031.04(n) in reserve, and makes other changes to update and clarify He-P 4031.03 and He-P 4031.04.

6. (b) Brief description of the groups affected:

Those affected by the rule include those general licensees who possess, acquire, receive, use or transfer or distribute self-luminous products containing radium-226 to properly dispose of the material.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

Rule	RSA or Statute Implemented by Rule
He-P 4031.03(b) intro, (b)(4) & (f)	10 CFR 40.21, 40.22, 40.25
He-P 4031.04(e) intro., (e) (10) intro., (e)(10)d. (e)(15), (h) intro., (h)(2), (n) [deleted], (p), (q), (r) intro., (r)(2) & (3), (5), (u), (v) intro. & (v)(1)	10 CFR 31.3, 31.4, 31.5, 31.7, 31.8, 31.9 & 31.10
He-P 4031.06	10 CFR 31.12

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name: **Catherine Bernhard** Title: **Rules Coordinator**
Address: **Dept. of Health and Human Services** Phone #: **271-9374**
Administrative Rules Unit Fax#: **271-5590**
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Concord, NH 03301

TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

The proposed rules may be viewed and downloaded at:

<http://www.dhhs.nh.gov/oos/aru/comment.htm>

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **Friday August 26, 2016**

☒ Fax

☒ E-mail

☐ Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Friday, August 19, 2016 at 8:30 a.m.**

Place: [**DHHS Brown Building, Auditorium, 129 Pleasant Street, Concord, NH**](#)

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # **16:139**, dated **July 21, 2016**

1. Comparison of the costs of the proposed rule(s) to the existing rule(s):

When compared to the existing rule, the proposed rule may increase costs for independently-owned businesses to the extent they own, possess, or transfer products containing radium-226.

2. Cite the Federal mandate. Identify the impact on state funds:

There is no federal mandate. However, pursuant to Section 274b of the Atomic Energy Act of 1954, as amended, the State of New Hampshire is an agreement state with the Nuclear Regulatory Commission (NRC). Accordingly, New Hampshire is required to have a program in place that is adequate and compatible with federal regulations. Abandonment of radium-226 is prohibited by 10 CFR 31.12(c)(2) and (c)(4), and so the proposed rule requires proper disposal consistent with the federal regulation.

3. Costs and benefits of the proposed rule(s):

A. To the State general or State special funds:

None.

B. To State citizens and political subdivisions:

None.

C. To Independently owned businesses:

There is a cost to any independent business that owns, possesses, acquires, uses, or transfers radium-226 or products containing radium-226 such as smoke detectors or certain time pieces. The rule requires these businesses to properly dispose of the products. The cost of disposal is often the cost of shipping the product back to the manufacturer or having the product disposed of by a waste disposal contractor. The cost of proper disposal is indeterminable.

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposal modifies an existing program or responsibility, but does not mandate any fees, duties or expenditures on the political subdivisions of the state, and therefore does not violate Part I, Article 28-a of the N.H. Constitution.

PART He-P 4031 GENERAL LICENSES

~~Statutory Authority: RSA 125-F:5, V~~

Amend He-P 4031.03, effective 5-23-14 (Document #10604), by amending paragraph (b)(4) and by inserting new paragraph (f) so that He-P 4031.03(b) intro,(b)(4) and (f) are cited and read as follows:

He-P 4031.03 General Licenses - Source Material.

(b) Persons who receive, possess, use, or transfer source material pursuant to the general license issued in He-P 4031.03(a):

(4) Shall be subjected to the provisions in ~~He-P 4020, He-P 4030.01, He-P 4030.10(j) through (n), He-P 4030.15, He-P 4030.16, and He-P 4031.02~~ He-P 4001.03, He-P 4001.05, He-P 4001.07, He-P 4001.08, He-P 4003.01, He-P 4024, He-P 4030.15 through He-P 4030.17, and He-P 4031.03;

(f) No person shall initially transfer or distribute source material to persons generally licensed under He-P 4031.03(a)(1) or (a)(2), equivalent regulations of an Agreement State, or Nuclear Regulatory Commission, unless authorized by a specific license issued in accordance with He-P 4032.03(a)(1) and (a)(2), equivalent provisions of an Agreement Statement, or Nuclear Regulatory Commission 10 CFR 40.54. This prohibition shall not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally license by He-P 4031.03(a) before August 27, 2013 without specific authorization shall continue for 1 year beyond this date. Distribution shall also be continued until DHHS/RHS or the Nuclear Regulatory Commission takes final action on pending application for license or license amendments to specifically authorized distribution submitted on or before August 27, 2014.

Amend He-P 4031.04, effective 5-23-14 (Document #10604), by amending (e)(10)d., (e)(15), (h)(2), (p), (q), (r) intro., (r)(2) and (3), (s), (u), and (v)(1), and amending by deleting and holding in reserve paragraph (n), so that He-P 4031.03(e) intro., (e)(10) intro., and (e)(10)d., subparagraph (e)(15), (h) intro. and subparagraph (h)(2), (p), (q), (r) intro., (r)(2) and (3), (s), (u), and (v) intro., and subparagraph (v)(1) are cited and read as follows:

He-P 4031.04 General Licenses - Byproduct Material Other Than Source Material.

(e) Any person who owns, receives, acquires, possesses, uses, or transfers byproduct material in a device pursuant to the general license in He-P 4031.04(b) shall:

(10) Transfer byproduct material in a device pursuant to the general license in He-P 4031.04(b) if the general license holder:

d. Reports the transfer under He-P 4031.04(e)(9)~~(e)~~;

(15) Register each device containing at least 370 MBq (10 mCi) of cesium-137, 3.7 MBq (0.1 mCi) of strontium-90, 37 MBq (1 mCi) of cobalt-60, ~~or 37 MBq (1 mCi) of americium-241,~~ or 3.7 MBq (0.1 mCi) of radium-226, or any other transuranic, based on the activity indicated on the device label. Each address for a location of use, as described under He-P 4031.04(e)(16) of this section, represents a separate general licensee and requires a separate registration and fee;

(h) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium 147 contained in luminous safety devices for use in aircraft, provided:

(2) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the DHHS/RHS, or an Agreement State, ~~or a Licensing State~~ to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in section 32.53 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

(n) ~~A general license shall be issued to receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of He-P 4031.04(p), (q), and (s) to any person who holds a specific license issued by the DHHS/RHS which authorizes him to receive, possess, use, and transfer radioactive material~~[Reserved].

(p) The general licenses in He-P 4031.04(m), ~~(n)~~, and (o) shall apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission, pursuant to section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued to the manufacturer by the DHHS/RHS, or an Agreement State, ~~or a Licensing State~~ pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the U.S. Nuclear Regulatory Commission.

(q) The general licenses provided in He-P 4031.04(m), ~~(n)~~ and (o) shall be subject to the provisions of He-P 4001 through He-P 4003, He-P 4019 through He-P 4023, He-P 4030.10, He-P 4030.16, He-P 4030.17 and He-P 4037.

(r) Persons who own, receive, acquire, possess, use and transfer one or more calibration or reference sources pursuant to He-P 4031.04(m), ~~(n)~~, or (o):

(2) Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements or a substantially similar statement which contains the information called for in the following statement:

~~a.~~ "The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.
CAUTION-RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS (AMERICIUM 241) or (PLUTONIUM~~RADIUM-226~~, as appropriate) ~~or other named material~~
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE
(Name of Manufacturer or ~~Importer~~Initial Transferor)"; ~~and~~

~~b. "The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of a Licensing State. Do not remove this label.
CAUTION RADIOACTIVE MATERIAL~~

~~— THIS SOURCE CONTAINS RADIUM 226~~
~~— DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE~~
~~— (Name of Manufacturer or Importer)";~~

(3) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the DHHS/RHS, the U.S. Nuclear Regulatory Commission, or an Agreement State, ~~or a Licensing State~~ to receive the source;

(s) The general licenses in He-P 4031.04 He-P 4031.04(m), ~~(n)~~, and (o) shall not authorize the manufacture, import or export of calibration or reference sources containing americium-241 or radium-226.

(u) A general license shall be issued to own, receive, acquire, possess, use and transfer strontium 90 contained in ice detection devices, provided each device contains not more than fifty microcuries of strontium 90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued by the DHHS/RHS, or an Agreement State, ~~or a Licensing State~~ to the manufacturer of such device pursuant to licensing requirements equivalent to those in section 32.61 of 10 CFR Part 32 of the regulations of the Nuclear Regulatory Commission.

(v) Persons who own, receive, acquire, possess, use, or transfer strontium 90 contained in ice detection devices pursuant to the general license in He-P 4031.04(u) shall:

(1) Upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license or equivalent licensing document from the Nuclear Regulatory Commission, or an Agreement State, ~~or a Licensing State~~ to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of those rules;

Adopt He-P 4031.06, to read as follows:

He-P 4031.06 General License for Certain Items and Self-luminous Products Containing Radium-226.

(a) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with provisions of He-P 4031.06(b), (c), and (d), radium-226 contained in the following products manufactured prior to November 30, 2007.

(1) Antiquities originally intended for use by the general public. For the purposes of He-P 4031.06(a)(1), antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads;

(2) Intact timepieces containing greater than 37 kBq (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces;

(3) Luminous items installed in air, marine, or land vehicles;

(4) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time;

(5) Small radium sources containing no more than 37 kBq (1 microcurie) of radium-226. For the purposes of He-P 4031.06(a)(5), "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the DHHS/RHS.

(b) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in He-P 4031.06(a) are exempt from the provisions of He-P 4001.03, He-P 4019 through He-P 4023, and He-P 4030.10(j), to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under He-P 4031.

(c) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in He-P 4031.06(a):

(1) Shall notify the DHHS/RHS should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, shall be furnished to the DHHS/RHS within 30 days;

(2) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, shall be disposed of according to He-P 4023 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the DHHS/RHS;

(3) Shall not export products containing radium-226 except in accordance with U.S. Nuclear Regulatory Commission 10 CFR 110;

(4) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under He-P 4030, or equivalent regulations of an agreement state, or as otherwise approved by the U.S. Nuclear Regulatory Commission;

(5) Shall respond to written requests from the DHHS/RHS to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, the general licensee shall, within the same time period, request a longer period to supply the information by providing the DHHS/RHS, a written justification for the request.

(d) The general license in He-P 4031.06(a) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

Appendix

Rule	RSA or Statute Implemented by Rule
He-P 4031.03	10 CFR 40.21, 40.22, 40.25
He-P 4031.04(e) intro., (3)(10) intro., (e)(10)d. (e)(15), (h) intro., (h)(2),(n) [deleted], (p), (q), (r) intro., (r)(2) & (3), (5), (u), (v) intro. & (u)(11)	10 CFR 31.3, 31.4, 31.5, 31.7, 31.8, 31.9, and 31.10
He-P 4031.06	10 CFR 31.12